APR 0 5 2013

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K130340

1. Date of Submission: 01/27/2013

2. Sponsor

Weigao Orthopaedic Device Co., Ltd.
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Locking Bone Plates and Screws

Classification Name: Plate, Fixation, Bone
Common Name: Bone Plates
Class: Class II
Product Code: HRS
Regulation Number: 21 CFR 888.3030

Review Panel: Orthopedic

Classification Name: Screw, Fixation, Bone
Common Name: Bone Screws
Class: Class II
Product Code: HWC
Regulation Number: 21 CFR 888.3040
Review Panel: Orthopedic

Intended Use Statement:

Locking Bone Plates and Screws are intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

5. Predicate Device Identification

510(k) Number: K101400
Product Name: Locking Compression Plate
Manufacturer: Changzhou Orthmed Medical Instrument Co., Ltd

510(k) Number: K100721
Product Name: Locking Bone Screw
Manufacturer: Changzhou Orthmed Medical Instrument Co., Ltd

6. Device Description

The proposed products, Locking Bone Plates and Screws, contain (1) locking plats with various specifications, (2) locking screws with various specifications and (3) Various specific instruments.

The bone plates are used for internal fixation of bones, screws are used for fix the plates on the bones, and instruments are used for completing the surgery.

Locking Screws are available in two kinds, which are self-tapping and self-drilling. Both of them share the same dimensions and materials.

These devices are provided un-sterilized, but shall be sterilized via autoclave method to achieve Sterility Assurance Level of 10^{-6} by hospital prior to use.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates.

ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws.

ANSI/AAMI/ISO17665-1: 2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

8. Substantially Equivalent Comparison and Conclusion

Table III-1 General and Safety Comparison

ITEM	Proposed Device Locking Bone Plates and Screws	Predicate Device Locking Compression Plate K101400 Locking Bone Screw K100721
Product Code	Plate: HRS	Same
	Screw: HWC	Same
Regulation No.	Plate: 21 CFR 888.3030	Same
	Screw: 21 CFR 888.3040	Same
Class	Class II	Same
Regulation No.	Plate: 21 CFR 888.3030	Same
Intended Use	Locking Bone Plates and Screws are intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.	Similar
Sterilization	Method: Autoclave SAL: 10^{-6}	Same

Table III-2 Specifications and Performance Comparison

ITEM	Proposed Device Locking Bone Plates and Screws	Predicate Device Locking Compression Plate K101400 Locking Bone Screw K100721
Physical Specifications – Locking Bone Plates		
Number of Holes	2-24	Similar
Length	26-312 mm	Similar
Thickness	3.3 / 3.6 / 4.2 mm	Similar
Width	11 / 12.5 / 13.5 mm	Similar
Material	Titanium conforms to ASTM F67-06	Similar
Physical Specifications – Locking Bone Screws		
Diameters	3.5. 4.5, 5.0	Similar
Lengths	10~120mm	Same
Material	Ti6Al4V ELI conforms to ASTM F136	Same
Mechanical Performance		
Test items for bone plates	Static four point bending	Same
	Dynamic four point bending	Same
Test standard for bone plates	ASTM F 382-99	Same
Test items for bone screws	Torsional properties	Same
	Driving torque	Same
	Pull-out test	Same
Test standard for bone screws	ASTM F543-07	Same

Difference in intended use, and physical specifications between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Locking Bone Plates and Screws, is determined to be Substantially Equivalent (SE) to the predicate device, Locking Compression Plate (K101400), and Locking Bone Screw (K100721), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Weigao Orthopaedic Device Co., Ltd.
% Mid-Link Consulting Co., Ltd
Ms. Diana Hong
General Manager
P.O. Box 237-023, 200237 Shanghai
China

Letter dated: April 5, 2013

Re: K130340
Trade/Device Name: Locking Bone Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 7, 2013
Received: February 19, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K130340
Device Name: Locking Bone Plates and Screws

Indications for Use:

Locking Bone Plates and Screws are intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) OR ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices